REMARKS

I. STATUS OF THE CLAIMS

Claims 1, 3-5 and 11-35 were pending at the time of the Action. Claims 28-35 are withdrawn from consideration. Claims 3, 4, and 15-21 are canceled. Claims 1, 5, 11-14, and 22-27 are amended to further clarify the claims. Support for claim amendments can be found in the claims as originally filed. No new matter has been added. Claims 1, 5, 11-14, and 22-27 are currently under examination.

II. REJECTION UNDER 35 U.S.C. §103

The Action sets forth a number of rejections under 35 U.S.C. 103 related to the alleged unpatentability of the current claims, including:

(A) the rejection of claims 1, 4, 5, and 15-18 as being unpatentable over U.S. patent 6,465,430 (the '430 patent) in view of U.S. patent publication 20020018749 (the '749 publication), and further in view of U.S. publication 20040171068 (the '068 publication) and U.S. Patent 6, 153,596 (the '596 patent);

(B) the rejection of claim 3 as being unpatentable over the '430 patent in view of the '749 publication, the '068 publication and the '596 patent in view of U.S. Patent 5,011,771 (the '771 patent);

(C) the rejection of claims 11-13 as being unpatentable over the referenced cited in (B) above in further view of the '771 patent and U.S. Patent 5,705,614 (the '614 patent);

(D) the rejection of claim 14 as being unpatentable over the references cited in (B) above in further view of U.S. Patent 6,800,728 (the '728 patent);

(E) the rejection of claims 19, 20, 22, and 24-26 as being unpatentable over the references cited in (B) above in view of U.S. Patent 6,197,599 (the '599 patent);

(F) the rejection of claim 23 as being unpatentable over the references cited in (E) above in further view of the '771 patent and the '614 patent;

(G) the rejection of claim 21 as unpatentable over the references cited in (B) above in further view of U.S. Patent 7,091,046 (the '046 patent); and

(H) the rejection of claim 27 as being unpatentable over the references cited in (G) above.

Applicants respectfully traverse.

A. Claims 1, 4, 5, and 15-18 are patentable over the '430 patent in view of the '749 publication, and further in view of the '068 publication and the '596 patent

Claims are rejected 1, 4, 5, and 15-18 as being allegedly unpatentable over U.S. patent 6,465,430 (the '430 patent) in view of U.S. patent publication 20020018749 (the '749 publication), and further in view of U.S. publication 20040171068 (the '068 publication) and U.S. Patent 6, 153,596 (the '596 patent).

Obviousness requires a suggestion of all the elements in a claim (*CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 [68 USPQ2d 1940] (Fed. Cir. 2003)) and "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co.l v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 [82 USPQ2d 1385] (2007).

The current claims are directed to a device comprising at least two distinct peptoid binding elements. The cited references do not teach or suggest all elements of current claim 1. Applicants request withdrawal of the rejection.

B. Claim 3 is patentable over the '430 patent in view of the '749 publication, the '068 publication and the '596 patent in view of the '771 patent

The Action rejects claim 3 as being allegedly unpatentable over the '430 patent in view of the '749 publication, the '068 publication and the '596 patent in further view of the '771

patent – the '771 patent disclosing assays for antigens that bind at least two antibodies that recognize distinct epitopes of the antigen. Applicants note that claim 1 as amended above is directed to a device comprising distinct peptoid binding elements – incorporating the limitation of claim 3 into claim 1. Applicants traverse.

As stated above, obviousness requires a suggestion of all the elements in a claim (*CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 [68 USPQ2d 1940] (Fed. Cir. 2003)) and "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co.l v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 [82 USPQ2d 1385] (2007). And more than that, an obviousness inquiry requires that the Examiner follow the holding or guidance provided in *Graham v. John Deere* and compare the claimed invention as a whole to the prior art. This comparison leads to a finding of ***all the differences*** between the claimed invention and the prior art. It is clearly impermissible to ignore some differences or simply compare general principles that may or may not be shared depending upon how the comparison is made.

The Action states that Applicants' "invention is based on the discovery that high density will increase the likelihood of the multivalent binding between receptors and the target as some fraction of the possible pairs of molecules on the surface will have an appropriate geometry relative to one another to bind the target molecule (citation omitted)" (Action, page 3). Applicants note that while a general mechanism underlying certain aspects of the current invention is based upon the binding of two distinct binding elements to a target the inventor makes no claim of discovering the principle of multivalent binding and is certainly not claiming it here. The inventor is claiming an array of distinct peptoids that bind individually to a target

with low affinity or moderate affinity - a novel device for identifying targets in a sample. Thus, it is the device under scrutiny and not multivalent binding *per se*.

The fact that a claimed device and a prior art disclosure may share some aspects of a common general principle – although applied in a different way - does not obviate the unique construction of Applicants' claimed device. The description in the '430 patent discloses a recombinant receptor expressed by and purified from recombinant host cells that are used as a ***binding element***. The purified recombinant receptor binding element is immobilized forming a surface with a ***single binding element – not two or more distinct binding elements as currently claimed***. The surface having a single binding element is then contacted with a plurality of ligands in the form of a peptide library. Applicants note that in certain aspects of the '430 patent a target is a peptide complex presenting multiple copies of the same peptide. This target/binding element complex includes identical binding elements binding identical targets – ***in this situation or any other situation disclosed in the '430 patent the target is not bound by two distinct binding elements***. Thus, the teaching that "for multivalent ligand-receptor interaction, using higher receptor densities will increase the likelihood of multivalent binding than at lower receptor densities, which thus increases the likelihood of isolating ligands with relatively lower affinity" and "the multivalent binding permits the detection of binding events of low intrinsic affinity" are not relevant to the currently claimed device and do not teach or describe all elements of the claimed invention or render the claimed invention obvious to one of skill in the art.

The essence of the '430 teaching is based upon the concept of discovering individual high affinity ligands that are or may be suitable as therapeutic TPO receptor ligand. The '430 patent teaches that peptides with a low-affinity may be discovered, but these peptides are mere

intermediates in identifying high affinity ligands for the TPO receptor. With all due respect, the Examiner appears to have taken the single paragraph referencing "multivalent binding" out of context. One of ordinary skill in the art would read the '430 patent as teaching methods and compositions of identifying certain high affinity ligands that bind to a certain receptor. Applicants' believe that the "concept" of multivalent binding as stated in the '430 patent is not identical to the concept as utilized in Applicants' invention. In fact, the principles are reversed in the two situations. In the '430 patent the receptors ("targets") are displayed in an array not the peptides ("binding elements") - the exact opposite of Applicants' invention, which has peptoids ("binding elements") bound to the support, not the receptors ("targets").

Applicants also respectfully disagree with the Examiner's assertion that the '430 patent discloses the same invention or discloses the same discovery as Applicants'. Applicants respectfully suggest that the claimed invention is far more than a recognition regarding spacing between receptors. Applicants' discovery is based upon the inventive "recognition" that even low and moderate affinity ligands can be useful, not just as lead compounds to be optimized, but in their own right when arranged on a support platform to screen against or assay biological targets (*e.g.*, as a diagnostic device). Applicants also note that the density of the peptoids arranged on the array can vary considerably depending upon the target. The claims do not require high density as clearly disclosed in the specification.

Thus, it is clear that the '430 reference, when viewed in its entirety, does not teach or suggest anything close to Applicants' claimed invention nor can it serve as a primary reference for an obviousness rejection. Instead, the '430 patent simply teaches methods of identifying peptides and peptide mimetics that are high affinity ligands for a particular receptor. There is no teaching or suggestion in the '430 patent to place the high affinity ligands on a support to screen

against the receptor in a sample. One of ordinary skill in the art would have no guidance and undue experimentation would be required to go from the concepts expressed in the '430 patent to an invention that would be close to or identical to Applicants' claimed invention.

The Action supplements the teachings of the '430 patent by citing the '749 publication, the '068 publication, the '596 patent, and the '771 patent, each of which fail to remedy the deficiency of the '430 patent.

The '749 publication describes the production of ***polyvalent antibodies, not peptoids***. These polyvalent antibodies are high molecular weight complexes relative to peptoids and are preselected to bind a particular epitope. Thus, the '749 publication does not describe or suggest distinct peptoid binding elements having low or moderate affinity for a target molecule. Any individual peptoid ligand arranged on Applicants' array is, once again, the polar opposite of the polyvalent antibodies described in the '749 publication. Applicants would like the Examiner to reconsider her position with respect to the use of the general concept of avidity as a basis to reject Applicants' claims. The combination of the entire teaching of the '430 patent and the disclosure in the '749 publication does not render Applicants' claims or any single claim obvious. In other words, the '749 publication does not remedy the deficiency of the '430 patent.

The '068 publication describes the localization of single binding elements that bind single ligands (monoclonal antibodies) in an array format, this configuration of an array does not describe the distribution of two distinct binding elements that cooperatively bind a target. Therefore, the '068 publication does not remedy the deficiency of the '430 patent.

The '596 patent relates to and teaches improved methods for introducing nucleic acid into cells. The '596 patent describes generally peptoid arrays for identifying a specific peptoid with a specific binding affinity. The '596 patent does not describe distribution of two distinct peptoid

binding elements that cooperatively bind a target. The combination of the teachings of the '430 patent and the '596 patent do not lead to or suggest the claimed invention. Furthermore,, the '596 patent does not remedy the deficiency of the '430 patent.

The '771 patent is advanced for the proposition that a multi-epitope target, *i.e.*, an antigen that is bound by multiple antibodies, somehow renders obvious two distinct peptoid binding elements that cooperatively bind a target. The Action fails to provide a sufficient reason as to what would have prompted a person of ordinary skill in the relevant field to substitute the disclosed antibodies – polypeptides that have evolved to specifically bind an epitope – with synthetic peptoid binding elements in the way the claimed invention does. The progression from antibody/antigen interaction to peptoid/target interaction is difficult to follow. An antibody is a complex polypeptide that binds a defined peptide - the antibody is pre-selected for specifically binding a particular polypeptide (an anti-Alpha-fetoprotein antibody will bind Alpha-fetoprotein). In contrast, a peptoid element of the current invention is not selected for specific binding of a particular protein or target. There is no explanation in the Action as to how or why one of skill would have taken the teaching of an immunoassay using two monoclonal antibodies (entities that are selected for specific binding of a target) and transferred such an idea to synthetic peptoids. Peptoids and monoclonal antibodies are very different compositions and the mere statement that one of skill would use different binding partners does not establish a suggestion to modify the '430 patent by substituting antibodies with peptoids, even if viewed in light of the other supplemental references.

Applicants request the withdrawal of the rejection.

C. Claims 11-13 are patentable over the '430 patent in view of the '749 publication, and further in view of the '068 publication and the '596 patent in further view of the '771 patent and the '614 patent

If an independent claim is not obvious then claims that depend from the non-obvious claim cannot be obvious because they depend from a nonobvious claim. *In re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992)* ("[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious."). As described above and incorporated here by reference claim 1 is not obvious in light of the cited references thus claims 11-13 are not obvious. Applicants request the withdrawal of the rejection.

D. Claim 14 as being unpatentable over the '430 patent in view of the '749 publication, and further in view of the '068 publication and the '596 patent in further view of the '728 patent

If an independent claim is not obvious then claims that depend from the non-obvious claim cannot be obvious because they depend from a nonobvious claim. *In re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992)* ("[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious."). As described above and incorporated here by reference claim 1 is not obvious in light of the cited references thus claim 14 is not obvious. Applicants request the withdrawal of the rejection.

E. Claims 19, 20, 22, and 24-26 are patentable over the '430 patent in view of the '749 publication, and further in view of the '068 publication and the '596 patent in view of the '599 patent

If an independent claim is not obvious then claims that depend from the non-obvious claim cannot be obvious because they depend from a nonobvious claim. *In re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992)* ("[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious."). As described above and incorporated here by

reference claim 1 is not obvious in light of the cited references thus claims 19, 20, 22, and 24-26 are not obvious. Applicants request the withdrawal of the rejection.

F. Claim 23 is patentable over the '430 patent in view of the '749 publication, and further in view of the '068 publication and the '596 patent in view of the '599 patent in further view of the '771 patent and the '614 patent.

If an independent claim is not obvious then claims that depend from the non-obvious claim cannot be obvious because they depend from a nonobvious claim. *In re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992)* ("[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious."). As described above and incorporated here by reference claim 1 is not obvious in light of the cited references thus claim 23 is not obvious. Applicants request the withdrawal of the rejection.

G. Claim 21 as unpatentable over the '430 patent in view of the '749 publication, the '068 publication and the '596 patent in view of the '771 patent in further view of the '046 patent

If an independent claim is not obvious then claims that depend from the non-obvious claim cannot be obvious because they depend from a nonobvious claim. *In re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992)* ("[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious."). As described above and incorporated here by reference claim 1 is not obvious in light of the cited references thus claim 21 is not obvious. Applicants request the withdrawal of the rejection.

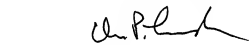
H. Claim 27 is patentable over the '430 patent in view of the '749 publication, the '068 publication and the '596 patent in view of the '771 patent in further view of the '046 patent

If an independent claim is not obvious then claims that depend from the non-obvious claim cannot be obvious because they depend from a nonobvious claim. *In re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992)* ("[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious."). As described above and incorporated here by reference claim 1 is not obvious in light of the cited references thus claim 27 is not obvious. Applicants request the withdrawal of the rejection.

III. CONCLUSION

In light of the foregoing, Applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned attorney at (512) 536-3167 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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